

Remarks/Arguments

Claims 1 to 18 were pending. By this Amendment, claims 1, and 3-6 have been cancelled and claims 2, 7-9, 11 and 14 have been amended. As no new matter has been added thereby, entry of the amendments is respectfully requested. Claims 2 and 7-18, as amended, are now pending and before the Examiner.

The Examiner objected to the specification in that it contains numerous incorporations by references and requested that the specification be amended to include such material in the specification.

In response, applicants traverse the objection. Incorporation by reference is specifically allowed by the rules, whether they are “numerous” or not, and the Examiner has provided no basis for concluding that any of the incorporated references, let alone all of them, are “essential material” and improper. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the objection.

The Examiner rejected claims 1-2, 4 and 6-18 as allegedly not enabled under 35 U.S.C. § 112, first paragraph.

In response, applicants have amended claims 2 and 14 to respond to the rejection, but also traverse the rejection as improper as set forth below. “When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement”. *In re Wright*, 27 U.S.P.Q. 1510, 1513 (Fed. Cir. 1993)(emphasis added).

In making this rejection, the Examiner alleges that the term “prevent” requires absolute success. Applicants respectfully disagree and request that the Examiner explain why prevention requires absolute success (if so, how can this be proven?), but treatment somehow does not? Applicants maintain that this is an unreasonable interpretation of the meaning of prevention and is accordingly improper. As the Board pointed out in *Ex parte Cho*, Appeal No. 2001-2646 (Bd. Pat. App. & Int. 2002)(nonprecedential)(copy enclosed for the Examiner’s convenience), on page 7, “The examiner has indicated that the claimed methods ‘would not be rejected if limited to “treating” pain, asthma and inflammation. ... Logically, if the recited compounds are useful for treating conditions such as pain and inflammation once they exist, they would also be expected to be effective in preventing pain and inflammation, if they were administered before the onset of pain or inflammation.” (emphasis in original). Applicants note that the Office has been repeatedly reversed for rejecting for lack of enablement claims directed to compounds having demonstrated pharmaceutical and biological activity. See M.P.E.P. § 2107 (particularly §§ 2107.01 III/IV and 2107.03, discussing the relationship of the utility and enablement requirements and the role of the FDA) and § 2164 (particularly § 2164.06). According, applicants respectfully request that the Examiner reconsider and withdraw the rejection.

The Examiner also rejected claims 1-2, 4-7 and 14-17 as allegedly anticipated under 35 U.S.C. § 102(b) over De Gasparo *et al.* (WO 01/76573), in light of Robl *et al.* (U.S. Patent Appl. Pub. No. 2002/0013334).

In response, applicants traverse the Examiner’s rejection. De Gasparo *et al.* does not specifically disclose the combination of telmisartan and atorvastatin anywhere and the Examiner has not pointed out how De Gasparo *et al.* thereby anticipates the

claimed invention. Accordingly, the anticipation rejection should be reconsidered and withdrawn.

The Examiner also rejected claims 1-18 as allegedly unpatentable under 35 U.S.C. § 103(a) over De Gasparo *et al.*, in light of Robl *et al.*, in view of Cecil's Textbook of Medicine (2000), Harlan *et al.* (U.S. Patent Appl. Pub. No. 2001/0006656), and Bohm *et al.* (WO 02/15891*).

Applicants respectfully traverse the rejection. A *prima facie* case of obviousness requires the satisfaction of three criteria: (i) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings; (ii) there must be a reasonable expectation of success; and (iii) the references when combined must teach or suggest all of the claim limitations. See M.P.E.P. § 2143. As explained above, De Gasparo *et al.* does not disclose or suggest the specific combination of telmisartan and atorvastatin anywhere, nor does Robl *et al.*, Cecil's Textbook of Medicine, Harlan *et al.*, nor Bohm *et al.* provide what De Gasparo *et al.* lacks in providing a motivation, reasonable expectation of success, or teaching or suggestion of all of the claim limitations of the claimed invention.

Furthermore, neither De Gasparo *et al.*, Robl *et al.*, Cecil's Textbook of Medicine, Harlan *et al.*, nor Bohm *et al.* teach or suggest that telmisartan increases the expression of genes regulated by the PPARGgamma receptor, i.e., an activity known from antidiabetic drugs, which is the reason that telmisartan is a preferred combination partner for atorvastatin in the treatment of, e.g., diabetes, and this

* In the Office Action WO 02/15892 seems to be a typographical error for WO 02/15891, which is consistent with the copy of the reference enclosed and the first inventor's name. Clarification is requested in the next Office Action.

metabolic activity appears to be unique for telmisartan. Furthermore, neither Harlan *et al.* (disclosing an aerosol formulation of statins), nor Bohm *et al.* (disclosing a combination of telmisartan with ACE inhibitors) do not disclose, suggest, or hint at telmisartan combinations with statins. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

The Examiner also provisionally rejected claims 1-18 for nonstatutory obviousness-type double patenting over claims 1-35 of U.S.S.N. 10/757,015, in view of Harlan *et al.*; provisionally rejected claims 1, 4-5, 7-11 and 14-16 for nonstatutory obviousness-type double patenting over claims 1-10, 12-15, and 18 of U.S.S.N. 10/899,784; and provisionally rejected claims 1-2, 4-7, and 12-18 for nonstatutory obviousness-type double patenting over claims 1 to 21 of U.S.S.N. 11/300,947 in view of Drug Facts and Comparisons (1996).

In response, with regard to U.S.S.N. 10/757,015, applicants undertake to file a terminal disclaimer should (1) the instant claims be found otherwise allowable, and (2) applicants determine that U.S.S.N. 10/757,015 poses a double patenting issue at that time. In addition, applicants traverse the remaining provisional double patenting rejections as the Examiner has failed to establish a *prima facie* case of obviousness as required for such double patenting rejections using these applications. With regard to U.S.S.N. 10/899,784, in making this provisional rejection, the Examiner states that “a species will always anticipate a claim to a genus”. This rule, however, does not mean that a genus [U.S.S.N. 10/899,784] always anticipates or renders obvious a species [the instant application] and the Examiner’s logic is fallacious and improper. With regard to U.S.S.N. 11/300,947, it claims a combination of telmisartan + HCTZ (diuretic): since it claims no statin, it is unclear how the claims of U.S.S.N. 11/300,947 render the instant claims obvious. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Application No. 10/757,295
Response dated September 19, 2006
Reply to Office communication of March 31, 2006

Applicants submit that all the pending claims are allowable and respectfully solicit a Notice of Allowance for all of the pending claims. If the Examiner feels that a telephone interview would be helpful in advancing prosecution of this application, the Examiner is invited to contact the attorney below.

Respectfully submitted,

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Application No. 10/757,295
Response dated September 19, 2006
Reply to Office communication of March 31, 2006

Attachment

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 31

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte SUNG Y. CHO,
THOMAS A. CROWELL,
BRUCE D. GITTER,
PHILIP A. HIPSKIND,
J. JEFFRY HOWBERT,
JOSEPH H. KRUSHINSKI JR.,
KAREN L. LOBB,
BRIAN S. MUEHL, and
JAMES A. NIXON

Appeal No. 2001-2646
Application No. 08/463,951

ON BRIEF

Before WINTERS, WILLIAM F. SMITH, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 7-10, 12, 14, 16, 18, 20, 21, 28-42, 49-59, 61, 62, 64, and 65, all of the claims remaining. Claims 11, 13, 15, 17, and 19 are also pending;

the examiner has indicated that these claims would be allowable if rewritten in independent form. See Paper No. 18, mailed June 16, 2000, page 4.

Claims 58 and 61 are representative of the subject matter on appeal are reproduced in the attached appendix.

The examiner relies on the following references:

Cho et al. ('009) 5,530,009 Jun. 25, 1996

Rouissi et al. (Rouissi), "Selectivity and Specificity of New, Non-peptide, Quinuclidine Antagonists of Substance P," Biochemical and Biophysical Research Communications, Vol. 176, No. 2, pp. 894-901 (1991)

Kucharczyk et al. (Kucharczyk), "Tetrapeptide Tachykinin Antagonists: Synthesis and Modulation of the Physicochemical and Pharmacological Properties of a New Series of Partially Cyclic Analogs," J. Med. Chem., Vol. 36, pp. 1654-1661 (1993)

Maggi et al. (Maggi), "Tachykinin receptors and tachykinin receptor antagonists," J. Auton. Pharmacol., Vol. 13, pp. 23-93 (1993)

Claims 7-10, 12, 14, 16, 18, 20, 21, 28-42, 49-59, 61, 62, 64, and 65 stand rejected under 35 U.S.C. § 112, first paragraph, as nonenabled.

Claims 7-9, 20, 21, 28-30, 36, 39, 49-51, 57-59, 61, 62, 64, and 65 stand rejected for obviousness-type double patenting over the claims of U.S. Patent 5,530,009.

We affirm the rejection for obviousness-type double patenting and reverse the rejection for nonenablement.

Background

Tachykinins are a family of peptides that share a common amidated carboxy-terminal sequence. See the specification, page 1. "Tachykinins are widely distributed in both the central and peripheral nervous systems, are

released from nerves, and exert a variety of biological actions, which, in most cases, depend upon activation of specific receptors expressed on the membrane of target cells." Id., page 2.

The specification discloses that the tachykinin known as substance P is believed to be "involved in neurotransmission of pain sensations, including the pain associated with migraine headaches and with arthritis." Id. Tachykinins "have also been implicated in gastrointestinal disorders and diseases of the gastrointestinal tract such as inflammatory bowel disease." Id. The specification provides an extensive list of other disorders that are disclosed to be "associated with an excess of tachykinins." See pages 126-129.

Tachykinin receptor antagonists have been the subject of research as potential therapeutic agents. See id., page 2. "The earliest tachykinin receptor antagonists were peptide derivatives. These antagonists proved to be of limited pharmaceutical utility because of their metabolic instability." Id., pages 2-3. The specification discloses "a class of potent non-peptide tachykinin receptor antagonists." Page 3. The specification provides 177 exemplary compounds and shows that they have varying affinities for the NK-1 and NK-2 tachykinin receptors when assayed in an in vitro test. See pages 44-110 (exemplary compounds) and pages 111-126 (in vitro binding assays and results).

Discussion

The claims are directed to compounds corresponding to a subgenus of the disclosed class of tachykinin receptor antagonists; specifically, those having a piperidinyl or piperazinyl moiety in the R¹ position. The claims also encompass

"pharmaceutically acceptable salt[s] or hydrate[s]" of the claimed compounds. See, e.g., claim 58. Other claims are directed to pharmaceutical compositions comprising the compounds and methods of treating numerous disorders using the compounds. The examiner rejected all of the claims except claim 21 for nonenablement and rejected most of the claims for obviousness-type double patenting.

1. Enablement

The examiner rejected all of the claims except claim 21 as nonenabled. With regard to all of the rejected claims, the examiner's position, as we understand it, was that the working examples provided in the specification showed only an acetyl or t-butoxycarbonyl group at this position, while the claim encompassed "a variety of unrelated functional groups such as phenoxy, morpholino, piperazino, piperadino, indoliny, isoquinoliny, benzothienyl, etc. as well as substituted derivatives thereof directly or indirectly attached to the C(O) group in the main formulae." Examiner's Answer, page 5. The examiner cited Appellants' own data as "show[ing] much structure sensitivity at this location," and argued that certain nonelected compounds with a piperazino or piperadino moiety at R7 had IC50 values "a thousandfold higher than the nanomolar ranges (10^{-9}) reported for instant alkanoyl derivatives." Examiner's Answer, pages 5-6. The examiner concluded that the disclosure was not representative of the scope of the claims and rejected the claims for lack of enablement. Id., page 6.

"When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to

why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement." In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). In this case, we conclude that the examiner has not carried the initial burden of showing prima facie nonenablement.

With respect to the ground of rejection based on the scope of the "R7" group, the basis of the rejection seems to be that (1) the scope of the functional groups recited in the claims for this position is much broader than the working examples in the specification, and (2) the effect of substituting other moieties for the exemplified groups is unpredictable. Thus, the examiner apparently concluded that the claims are nonenabled because they encompass inoperative embodiments.

This is not an adequate basis to support a conclusion of nonenablement. See Atlas Powder Co. v. E.I. Du Pont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 414 (Fed. Cir. 1984): "Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid. 'It is not a function of the claims to specifically exclude . . . possible inoperative substances . . .'" (quoting In re Dinh-Nguyn, 492 F.2d 856, 858-59, 181 USPQ 46, 48 (CCPA 1974)). It is only "if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, [that] the claims might indeed be [nonenabled]." Id.

The examiner's basis of the rejection is that the scope of the R7 groups recited in the claims encompassed a variety of functional groups that are "unrelated" to the exemplified acetyl and t-butoxycarbonyl groups. This may well be true, and the claims may indeed encompass inoperative embodiments, but the examiner has not reasonably explained why the scope of R7 groups recited in the claims would have required undue experimentation to distinguish the operative embodiments from potentially inoperative ones. Therefore, she has not carried the initial burden of showing that the claims are not enabled.

With regard to the method-of-treatment claims (claims 28-42, 61, and 62) the examiner cited two other bases for nonenablement. First, "all method claims[,] even those directed to specific uses (some [of] which the examiner indicated would not be objected to if limited to just treating) embrace 'preventing'." Examiner's Answer, page 7 (emphasis in original). In addition, the examiner objected to the "huge list of disorders which is covered by the main claim (61) and includes the list presented on pages 126-129 [of the specification] which includes whole classes of disorders such as all forms of dementia including Alzheimer's, Down's Syndrome, multiple sclerosis and all other neurodegenerative disorders, all types of gastrointestinal disorders, all op[h]thalmic diseases and the list goes on and on." Examiner's Answer, page 7.

The examiner cited Maggi as "mentioning a lot of potential uses" but concluding that, while tachykinin antagonists may be useful for certain human diseases, they were not (as of Appellants' filing date) "a recognized class for human therapy." Id., page 8. The examiner cited Hoffman v. Klaus, 9 USPQ2d

1657 (Bd. Pat. App. Int. 1988) and Ex parte Powers, 220 USPQ 924 (Bd. Pat. App. Int. 1982), as providing "the standard of testing needed to show in vivo efficacy." Examiner's Answer, page 8. The examiner apparently concluded that in vivo efficacy for the claimed methods must be shown, because "[o]therwise, the huge lists of disorders urged in the specification (claims such as 61 are virtually nonlimiting) [are] simply an invitation to experiment which is not in compliance with 35 USC 112, par.one." Id.

Here again, we conclude that this basis of the rejection fails to carry the examiner's initial burden of showing nonenablement. First, the examiner has provided no explanation of why the recitation of "preventing" a disorder causes the claims to become nonenabled. The examiner has indicated that the claimed methods "would not be rejected if limited to 'treating' pain, asthma and inflammation. Examiner's Answer, page 8. Logically, if the recited compounds are useful for treating conditions such as pain and inflammation once they exist, they would also be expected to be effective in preventing pain or inflammation, if they were administered before the onset of pain or inflammation. The examiner has provided no reasoning to support a contrary conclusion.

In addition, the examiner has not provided sufficient evidence to support her position that the claimed methods of treatment are not enabled. See In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971) ("[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be

taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." (emphasis in original)).

The examiner cites Maggi and Rouissi as not providing "evidence that NK-1 antagonists (which is what applicants' compounds are) as a class or even individual compounds have such a range of uses," as claimed. See the Examiner's Answer, pages 7-8. However, the examiner concedes that Maggi

mention[s] a lot of potential uses beginning on p. 60 through 66 for NK-1 antagonists including psychosis, neurodegenerative diseases such as Alzheimer's, convulsions, Crohn's disease, ocular disease, and irritable bowel syndrome [and] concludes on p. 67 that NK antagonists may be useful for certain human diseases.

Examiner's Answer, page 8.

The examiner cites no evidence contradicting Maggi, and indicating that NK-1 antagonists such as those disclosed in the instant specification would not be expected to be effective in treating the recited disorders. Since the examiner has conceded that Maggi suggests NK-1 antagonists have potential uses in treating a variety of disorders, the evidence of record appears to favor Appellants' position more than the examiner's.

The examiner may well be correct that Maggi and Rouissi do not show that NK-1 antagonists have the breadth of uses disclosed in the specification. But the examiner must do more than point to a lack of evidence supporting the breadth of the claims. The burden is not on the applicants to show that the disclosure in the specification is correct; the burden is on the examiner to show

that it is not. Pointing out a lack of independent evidentiary support is not enough to carry that burden. "[I]t is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure."

Marzocchi, 439 F.2d at 224, 169 USPQ at 370.

Finally, regardless of what was said in the Board decisions cited by examiner, treatment claims do not necessarily require a showing of in vivo efficacy to be enabled. See, e.g., Cross v. Iizuka, 753 F.2d 1040, 1051, 224 USPQ 739, 748 (Fed. Cir. 1985).

2. Obviousness-type double patenting

The examiner rejected some of the claims for obviousness-type double patenting, on the basis that they are directed to a genus that encompasses the species claimed in U.S. Patent 5,530,009. See the Examiner's Answer, pages 12-13.

Appellants concede that the '009 patent "claims a single, specific crystalline species . . . that is covered generically in the subject application." Appeal Brief, page 11. They argue, however, that a rejection for obviousness-type double patenting is not warranted because the application that matured into the '009 patent was filed after (the effective filing date of) the instant application, even though it issued first. Appellants cite In re Braat, 937 F.2d 589, 19 USPQ2d

1289 (Fed. Cir. 1991), for the following proposition: "In order for a proper double patenting rejection to stand, the claims of the later-filed species application must not be patentably distinct from the claims of the earlier-filed generic application (the subject application)." Appeal Brief, page 11. Put another way, Appellants argue that the present case is subject to a "two-way" test of double patenting, and that under such a test, the rejection is improper.

As Appellants may be aware, in the time since Braat was decided, the Federal Circuit has clarified the circumstances which require a two-way test for double patenting. See In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 58 USPQ2d 1869 (Fed. Cir. 2001). In Berg, the court characterized the two-way test as "a narrow exception to the general rule of the one-way test." 140 F.3d at 1431, 46 USPQ2d at 1229. The court held that the two-way test was appropriate only if (1) the applicant could not have filed both sets of claims in a single application and (2) "the PTO is solely responsible for the delay in causing the second-filed application to issue prior to the first." Id. at 1437, 46 USPQ2d at 1233. In Berg, the court concluded that the applicant could have filed both sets of claims in a single application, and therefore a one-way test for double patenting was appropriate. See id.

In Eli Lilly v. Barr Labs., the court reiterated that "[t]he two-way test is only appropriate in the unusual circumstance where, inter alia, the United States Patent and Trademark Office ('PTO') is 'solely responsible for the delay in causing the second-filed application to issue prior to the first.'" 251 F.3d at 969,

58 USPQ2d at 1878 (quoting Berg, emphasis added by the Lilly court). The Lilly court held that the PTO was not solely responsible for the delay in that case, because

the [first-filed, later-issued] '549 patent issued in December 1986, approximately eight months after a continuation-in-part was filed, which stemmed from a continuation application, which in turn stemmed from a divisional of the '379 application that was filed in January 1974. Further, an expert hired on behalf of Lilly . . . , in discussing claim 7 of the '549 patent, stated: "[I]t is true that the claim could have been presented earlier. . . ." This statement indicates that the delay was not solely caused by the PTO.

Id. at 969 n.7, 58 USPQ2d at 1878 n.7. Thus, according to Berg and Lilly, if the PTO is not solely responsible for the delay causing the first-filed application to issue later, then the application claims are subject to a one-way test to determine whether a rejection for double patenting is appropriate.

In this case, Appellants have caused at least part of the delay that has resulted in this application still being pending, even though a later-filed application has matured into the '009 patent. First, the instant application is a divisional of application 08/153,847. The '847 application was subject to a restriction requirement (see the '847 application's Paper No. 7, mailed August 11, 1994). As a result of that restriction, Appellants elected to pursue certain claims and other claims, including those now on appeal, were withdrawn from further consideration.

As noted, the restriction requirement was mailed August 11, 1994; in addition, the examiner stated that "[d]uring a telephone conversation with Mr. Gaylo on August 4, 1994 a provisional election was made with traverse to

prosecute the invention of [Group] III." See Paper No. 7, page 4. Thus, Appellants were apparently on notice in August 1994 of the need to file one or more divisional applications in order to pursue all of the claims in the original application. Appellants, however, did not file the instant divisional application until June 5, 1995, roughly ten months after they were put on notice of the need to do so. Since Appellants were on notice of the need to file a divisional to pursue the instant claims as of August 1994, yet did not file until June 1995, they are responsible for about ten months' worth of the delay in the instant application.

In addition, when Appellants did get around to filing the instant application, they filed it with a specification that was missing page 7 and had an illegible page 6; for this reason, the PTO initially refused to accord the application a filing date. See Paper No. 2, mailed July 24, 1995. Appellants' filing of a defective specification resulted in the need for a petition to be accorded a filing date, which precipitated a chain of events that resulted in the instant application not being accorded its filing date, and forwarded for examination, until March 18, 1997. See Paper No. 7, mailed March 18, 1997. While not all of this delay is directly attributable to the defective specification, Appellants must share in the responsibility for the delay.

Finally, and most egregiously, Appellants neglected to respond to an Office action in the present application, allowing it to go abandoned. See Paper No. 9, mailed January 6, 1998. Appellants then waited nearly twenty-one months before filing a petition to revive the application and restore it to pending status. See Paper No. 10, filed Sept. 30, 1999. Even then, the first petition was filed

without the required terminal disclaimer, and therefore had to be re-filed before the application could be revived. See Paper No. 13, mailed Oct. 25, 1999 (first petition dismissed); Paper Nos. 14 and 15, filed Feb. 15, 2000 (second petition and terminal disclaimer);¹ and Paper No. 17, mailed April 10, 2000 (petition granted). Appellants declared that their delay in filing a response was unintentional, but nonetheless that delay was indisputably Appellants' fault. Appellants are therefore responsible for a delay in prosecution of at least 25 months, i.e., the period of time between the notice of abandonment of the application and the filing of a grantable petition to revive.

For all these reasons, we conclude that the PTO is not solely responsible for the delay that has caused this application to remain pending even though the '009 patent has issued. A one-way test for double patenting is therefore appropriate: the only relevant issue is whether the application claims are patentably distinct from the claims of the issued patent.

Appellants have conceded that the '009 patent "claims a single, specific crystalline species . . . that is covered generically in the subject application." Appeal Brief, page 11. A later claim "is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim." Lilly, 251 F.3d at 968, 58 USPQ2d at 1878. "[A] later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim." Id. at 971, 58 USPQ2d at 1880. The present generic claims are not

¹ Appellants were required to disclaim the terminal part of any patent issued on the instant application equivalent to the period of abandonment. The terminal disclaimer of record does not refer to the '009 patent and does not overcome the rejection for double patenting.

patentably distinct from the issued species claims. We therefore affirm the examiner's rejection for obviousness-type double patenting.

Summary

We agree with the examiner that instant claims 7-9, 20, 21, 28-30, 36, 39, 49-51, 57-59, 61, 62, 64, and 65 are not patentably distinct from the claims of the '009 patent; we therefore affirm the rejection for obviousness-type double patenting. However, the examiner has not adequately shown that practicing the instant claims would have required undue experimentation and we therefore reverse the rejection under 35 U.S.C. § 112, first paragraph. As a result, claims 10-19, 31-35, 37, 38, 40-42, 52-56 are not subject to any outstanding rejection.

AFFIRMED IN PART

Sherman D. Winters)	
Administrative Patent Judge)	
)	
)	
)	BOARD OF PATENT
William F. Smith)	
Administrative Patent Judge)	APPEALS AND
)	
)	INTERFERENCES
)	
Eric Grimes)	
Administrative Patent Judge)	

Appeal No. 2001-2646
Application No. 08/463,951

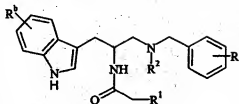
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Appendix

58. A compound of the formula



wherein:

R^1 is piperazinyl or piperidinyl;

which may be substituted with halo, C_1 - C_4 alkoxy, trifluoromethyl, amino, C_1 - C_4 alkylamino, di(C_1 - C_4 alkyl)amino, phenyl, piperazinyl, C_3 - C_8 cycloalkyl, benzyl, C_1 - C_4 alkyl, piperidinyl, pyrimidinyl, C_2 - C_6 alkanoylamino, pyrrolidinyl, C_2 - C_6 alkanoyl, or C_1 - C_4 alkoxy carbonyl; any one of which phenyl, piperazinyl, C_3 - C_8 cycloalkyl, benzyl, C_1 - C_4 alkyl, piperidinyl, pyrrolidinyl, C_2 - C_6 alkanoyl, or C_1 - C_4 alkoxy carbonyl groups may be substituted with halo, C_1 - C_4 alkyl, C_1 - C_4 alkoxy, trifluoromethyl, amino, C_1 - C_4 alkylamino, di(C_1 - C_4 alkyl)amino, or C_2 - C_4 alkanoylamino;

R^2 is $-CO-R^6$;

R^6 is hydrogen, C_1 - C_4 alkyl, C_1 - C_3 haloalkyl, phenyl, C_1 - C_3 alkoxy, C_1 - C_3 hydroxyalkyl, amino, C_1 - C_4 alkylamino, di(C_1 - C_4 alkyl)amino, or $-(CH_2)_q-R^7$;

q is 0 to 3;

R^7 is phenoxy, phenylthio, piperazinyl, piperidinyl, pyrrolidinyl, morpholinyl, indolinyl, indolyl, benzothienyl, benzoxfuranyl, quinolinyl, isoquinolinyl, phenyl- $(C_1$ - C_4 alkyl)-, quinolinyl- $(C_1$ - C_4 alkyl)-, isoquinolinyl- $(C_1$ - C_4 alkyl)-, benzoyl- C_1 - C_3 alkyl;

any one of which R⁷ groups may be substituted with halo, trifluoromethyl, C₁-C₄ alkoxy, amino, C₁-C₄ alkylamino, di(C₁-C₄ alkyl)amino, C₂-C₄ alkanoylamino, phenyl, piperazinyl, C₃-C₈ cycloalkyl, benzyl, piperidinyl, pyridinyl, pyrimidinyl, pyrrolidinyl, C₂-C₆ alkanoyl, C₁-C₄ alkyl, or C₁-C₄ alkoxycarbonyl;

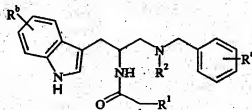
any of which phenyl, piperazinyl, C₃-C₈ cycloalkyl, benzyl, piperidinyl, pyridinyl, pyrimidinyl, pyrrolidinyl, C₂-C₆ alkanoyl, C₁-C₄ alkyl, or C₁-C₄ alkoxycarbonyl groups may be substituted with halo, trifluoromethyl, C₁-C₄ alkoxy, C₁-C₄ alkyl, C₁-C₄ alkylamino, di(C₁-C₄ alkyl)amino, or C₂-C₄ alkanoylamino;

R^a is halo, C₁-C₃ alkoxy, C₁-C₃ alkylthio, nitro, trifluoromethyl, or C₁-C₃ alkyl; and

R^b is hydrogen, halo, C₁-C₄ alkyl, C₁-C₄ alkoxy, trifluoromethyl, amino, C₁-C₄ alkylamino, or di(C₁-C₄ alkyl)amino;

or pharmaceutically acceptable salt or solvate thereof.

61. A method for the treatment or prevention of physiological disorder associated with an excess of tachykinins, which method comprises administering to a mammal in need of said treatment an effective amount of a compound of the formula



wherein:

R¹ is piperazinyl or piperidinyl;

which may be substituted with halo, C₁-C₄ alkoxy, trifluoromethyl, amino, C₁-C₄ alkylamino, di(C₁-C₄ alkyl)amino, phenyl, piperazinyl, C₃-C₈

cycloalkyl, benzyl, C₁-C₄ alkyl, piperidinyl, pyrimidinyl, C₂-C₆ alkanoylamino, pyrrolidinyl, C₂-C₆ alkanoyl, or C₁-C₄ alkoxycarbonyl; any one of which phenyl, piperazinyl, C₃-C₈ cycloalkyl, benzyl, C₁-C₄ alkyl, piperidinyl, pyrrolidinyl, C₂-C₆ alkanoyl, or C₁-C₄ alkoxycarbonyl groups may be substituted with halo, C₁-C₄ alkyl, C₁-C₄ alkoxy, trifluoromethyl, amino, C₁-C₄ alkylamino, di(C₁-C₄ alkyl)amino, or C₂-C₄ alkanoylamino;

R² is -CO-R⁶;

R⁶ is hydrogen, C₁-C₄ alkyl, C₁-C₃ haloalkyl, phenyl, C₁-C₃ alkoxy, C₁-C₃ hydroxyalkyl, amino, C₁-C₄ alkylamino, di(C₁-C₄ alkyl)amino, or -(CH₂)_q-R⁷;

q is 0 to 3;

R⁷ is phenoxy, phenylthio, piperazinyl, piperidinyl, pyrrolidinyl, morpholinyl, indolinyl, indolyl, benzothienyl, benzofuranyl, quinolinyl, isoquinolinyl, phenyl-(C₁-C₄ alkyl)-, quinolinyl-(C₁-C₄ alkyl)-, isoquinolinyl-(C₁-C₄ alkyl)-, benzoyl-C₁-C₃ alkyl;

any one of which R⁷ groups may be substituted with halo, trifluoromethyl, C₁-C₄ alkoxy, amino, C₁-C₄ alkylamino, di(C₁-C₄ alkyl)amino, C₂-C₄ alkanoylamino, phenyl, piperazinyl, C₃-C₈ cycloalkyl, benzyl, piperidinyl, pyridinyl, pyrimidinyl, pyrrolidinyl, C₂-C₆ alkanoyl, C₁-C₄ alkyl, or C₁-C₄ alkoxycarbonyl;

any of which phenyl, piperazinyl, C₃-C₈ cycloalkyl, benzyl, piperidinyl, pyridinyl, pyrimidinyl, pyrrolidinyl, C₂-C₆ alkanoyl, C₁-C₄ alkyl, or C₁-C₄ alkoxycarbonyl groups may be substituted with halo, trifluoromethyl, C₁-C₄ alkoxy, C₁-C₄ alkyl, C₁-C₄ alkylamino, di(C₁-C₄ alkyl)amino, or C₂-C₄ alkanoylamino;

R^a is halo, C₁-C₃ alkoxy, C₁-C₃ alkylthio, nitro, trifluoromethyl, or C₁-C₃ alkyl; and

R^b is hydrogen, halo, C₁-C₄ alkyl, C₁-C₄ alkoxy, trifluoromethyl, amino, C₁-C₄ alkylamino, or di(C₁-C₄ alkyl)amino;

or pharmaceutically acceptable salt or solvate thereof.